DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting is open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held November 8, 2005, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the

heading "Oncologic Drugs Advisory Committee (ODAC)." (Click on the year 2005 and scroll down to ODAC meetings.)

Agenda: The committee will discuss new drug applications approved under 21 CFR 314.500 and 601.40 (subparts H and subpart E, respectively, accelerated approval regulations) in an open session to do the following: (1) Review the status of phase IV clinical studies; (2) identify difficulties associated with completion of phase IV commitments; and (3) provide advice to sponsors to assist in the planning and execution of postmarketing commitments of newly approved drugs. The committee will discuss phase IV commitments of: (1) new drug application (NDA) 50–718, DOXIL (doxorubicin hydrochloride liposome injection, Johnson and Johnson Pharmaceutical Research and Development, L.L.C.) for the treatment of acquired immune deficiency syndrome (AIDS) related Kaposi's sarcoma in patients with disease that has progressed on prior combination therapy or in patients who are intolerant to such therapy; (2) NDA 20–221/S–002, ETHYOL for injection (amifostine, MedImmune Oncology, Inc.) for reducing the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced nonsmall cell lung cancer; (3) biologics license application (BLA) 103767/0, ONTAK (denileukin diftitox, Seragen Incorporated) for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the interleukin-2 receptor; (4) NDA 21–041, DEPOCYT (cytarabine liposome injection, SkyePharma Inc.) for the intrathecal treatment of lymphomatous meningitis; and (5) NDA 21–156, CELEBREX (celecoxib capsules, Pfizer, Inc.) for reducing the number of adenomatous colorectal polyps in familial adenomatous polyposis, as an adjunct to usual care (e.g., endoscopic surveillance, surgery); (6) NDA 21–174,

MYLOTARG (gemtuzumab ozogamicin for injection, Wyeth Pharmaceuticals, Inc.) for the treatment of patients with CD33 positive acute myeloid leukemia in first relapse who are 60 years of age or older and who are not considered candidates for other cytotoxic chemotherapy; and (7) BLA 103948/0, CAMPATH (alemtuzumab, ILEX Pharmaceuticals, L.P.) for the treatment of B-cell chronic lymphocytic leukemia (B-CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 1, 2005. Oral presentations from the public will be scheduled between approximately 2 p.m. to 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 1, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Johanna Clifford at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 10-6-05

October 6, 2005.

Jason Brodsky,
Acting Associate Commissioner for External Relations.

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